

REMARKS

I. Introduction

Applicant thanks Examiner Pepitone for his review and consideration of the present Application. In response to the non-final Office Action mailed March 30, 2010, Applicant submits the present amendment and remarks (“Response”). The Response cancels claim 28; amends claims 1-27, 29 and 31; and adds new claim 32. Support for these amendments may be found, among other places, in the claims as-filed. Upon entry of the Response, claims 1-27, and 29-32 are pending in the application. No new matter has been added by the Response.

The Response is believed to overcome all of the prior Office Action rejections, and allowance of the pending claims is respectfully requested.

III. Rejections based on 35 U.S.C. § 112

The Office Action rejected claims 22 and 23 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant has amended claim 22 to recite “said bone growth agent” rather than “said agent.” Applicant has amended claim 23 to recite “said chemotherapeutic agent” rather than “said agent.”

Applicant submits that these amendments overcome the § 112 rejection and requests withdrawal of the rejection.

IV. Rejections based on 35 U.S.C. § 102

The Office Action rejected claims 1-5, 7-8, 18, and 28-31 under 35 U.S.C. § 102(b) as being anticipated by U.S. Published Application No. 2002/0082362 to Brocchini *et al.*

(“*Brocchini*”). Applicant respectfully traverses this rejection in light of the foregoing amendments and the following remarks and requests that it be withdrawn.

Applicant has amended claim 1 to recite that the polyol residues are selected from the group consisting of polyesters, degradable carbonates, and polyamides. *Brocchini* does not disclose a block copolymer comprising polyols selected from polyesters, degradable carbonates, and polyamides. The Action acknowledges that *Brocchini* “does not [teach] a specific diol comprising polyesters” (Action, p. 5) and “does not [teach] a specific diol comprising a carbonate” (*Id.* at 6). The Action does not explicitly acknowledge that *Brocchini* does not disclose polyamides but does so implicitly by failing to reject dependent claim 12, which adds the limitation that the polyol is a polyamide, over *Brocchini*. For a reference to anticipate a claim under § 102, it must describe, either expressly or inherently, each and every element set forth in the claim. MPEP § 2131. *Brocchini* does not describe, either expressly or inherently, a block copolymer comprising polyols selected from polyesters, degradable carbonates, and polyamides, and therefore, does not describe each and every element set forth in independent claim 1. Accordingly, *Brocchini* does not anticipate independent claim 1, and claim 1 is patentable over *Brocchini*.

Claim 28 was canceled, rendering its rejection moot. Claims 2-5, 7-8, 18, and 29-31 depend from and further limit claim 1 or an intervening dependent claim. Accordingly, dependent claims 2-5, 7-8, 18, and 29-31 are patentable over *Brocchini* for at least the same reasons independent claim 1 is patentable, and may be patentable for additional reasons.

Accordingly, Applicant submits that claims 1-5, 7-8, 18, and 29-31 are in condition for allowance.

V. Rejections based on 35 U.S.C. § 103

The Office Action rejected claims 6, 9-17, and 19-27 under 35 U.S.C. § 103(a). Claims 6, 14, 17, and 19-26 were rejected as being unpatentable over *Brocchini*. Claims 9-10, 12-13, and 16 were rejected as being unpatentable over *Brocchini* further in view of U.S. Patent 5,665,831 to Neuenschwander *et al.* (“*Neuenschwander*”). Claim 11 was rejected as unpatentable over *Brocchini* further in view of U.S. Patent 6,503,991 to Shalaby (“*Shalaby*”). Finally, claims 15 and 27 were rejected as being unpatentable over *Brocchini* further in view of U.S. Patent 6,071,982 to Wise *et al.* (“*Wise*”).

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103, MPEP 2141, as revised after the Supreme Court Decision in *KSR International Co. v. Teleflex*, explain what is required where an obviousness rejection is made:

As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) [Determining the scope and content of the prior art]; and
- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. . . .

Office personnel fulfill the critical role of fact-finder when resolving the *Graham* inquiries. . . . Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. . . .

Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103.

MPEP §2141 (II).

For at least the reasons set forth below, the Office Action has failed to set forth a *prima facie* case of obviousness for the rejected claims. Applicant accordingly and

respectfully traverses these rejections and requests reconsideration in light of the foregoing amendments and the following remarks and withdrawal of the rejections.

A. The Present Application

In contrast with *Brocchini*, embodiments of the present application are directed to biodegradable polymers having a high mechanical strength for use in load bearing medical devices suitable for implantation in the body. Accordingly, the claimed subject matter recites a biodegradable segmented block copolymer comprising polyol residues selected from polyesters, degradable carbonates, and polyamides, having a molecular weight of at least 4000 Daltons, where the polyol residues are connected by acetal linkages. Neither *Brocchini* nor any other art of record provides such polyester, degradable carbonate, or polyamides connected by acetal linkages, and one of skill in the art would not be motivated to combine *Brocchini* with any other art of record to arrive at the claimed copolymers.

B. Claims 6, 14, 17, and 19-26 are Patentable over Brocchini

The Action has failed to present a *prima facie* case of obviousness at least because *Brocchini* does not teach or suggest all of the limitations of independent claim 1. Claims 6, 14, 17, and 19-26 depend from claim 1 or an intervening dependent claim and, therefore, incorporate the limitations of claim 1. As amended, claim 1 recites that the polyol is selected from polyesters, degradable carbonates, and polyamides. *Brocchini* does not teach or suggest a polyol selected from polyesters, degradable carbonates, and polyamides. The Action has thus failed to present a *prima facie* case of obviousness at least because *Brocchini* does not teach or suggest a polyol selected from polyesters, degradable carbonates, and polyamides.

For at least these reasons, claims 6, 14, 17, and 19-26 are not obvious in view of *Brocchini*. Applicant respectfully requests reconsideration and withdrawal of the rejection. Claims 6, 14, 17, and 19-26 are believed allowable.

C. Claims 9-10, 12-13, and 16 are Patentable over Brocchini further in view of Neuenschwander

Brocchini discloses degradable polyacetal polymers comprising a polyol block where the polyol is a polyether. (*Brocchini*, [0082]-[0086].) The Action acknowledges that *Brocchini* does not disclose a polyol selected from a polyester (as recited in claim 9) or a polyamide (as recited in claim 12). (Action, p. 5.) The Action relies on *Neuenschwander* to supply these missing teachings. *Neuenschwander* discloses biocompatible block copolymers having at least two chemically different block units: a polyether block unit and a polyester block unit. (*Neuenschwander*, 2:9-16.) The Action cites *Neuenschwander* as supplying a polyester or polyamide co-polymer and argues that it would be obvious to modify *Brocchini* by substituting the polyesters of *Neuenschwander* for the polyether of *Brocchini*. Applicant disagrees with the Action's assertion that *Neuenschwander* discloses polyamides. Furthermore, one of skill in the art would not be motivated to combine *Brocchini* and *Neuenschwander* because these references are not analogous art and because making the substitution suggested by the Action would render the invention of *Brocchini* inoperable for its intended purpose. Moreover, contrary to the Action's argument, *Neuenschwander* does not provide motivation to make the suggested modification.

The Examiner points to *Neuenschwander's* disclosure of "ring opening polymerization of . . . lactams" as disclosing polyamides. Based on context, *Neuenschwander's* use of the word "lactam" was clearly a typographical error and cannot be

considered disclosure of polyamides. The entire sentence in which the word lactam appears is: “Preferred cyclic *esters* of this type are (L,L)-dilactide, (D,D)-dilactide, (D,L)-dilactide, diglycolide or the preferred *lactams* B-(R)-butyrolactone, B-(D)-butyrolactone, B-rac-butyrolactone and ε-caprolactone or mixtures thereof.” (emphasis added) (*Id.* 2:31-35.) The sentence is clearly referring to cyclic esters, which are chemically different from lactams. Moreover, the “preferred lactams” listed are all lactones, which are cyclic esters and chemically different from lactams. One of skill in the art would immediately understand that *Neuenschwander’s* use of the word “lactam” was an error and would not understand *Neuenschwander* to disclose polyamide polyols. Even if *Neuenschwander’s* inadvertent disclosure of lactams is sufficient to disclose polyamides, the disclosure of *Neuenschwander* is certainly not enabling. *See Impax Labs. Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1315-16 (Fed. Cir. 2008) (affirming a district court holding that a prior art reference was not enabling for a particular embodiment where excessive experimentation would have been required and where the trial court found that the embodiment was not meaningfully discussed and “rejected the notion that the mere mention of [the embodiment] is sufficient to put one skilled in the art in the possession of the claimed invention.”). Thus, the combination of *Neuenschwander* and *Brocchini* does not provide each and every element of at least claim 12, which recites that the polyol is a polyamide.

Moreover, “to rely on a reference under 35 U.S.C. 103, it must be analogous prior art.” MPEP 2141.01(a). The Federal Circuit has announced a two-part test for determining whether references are within the appropriate scope of the art. *See In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986). First, it must be determined whether the reference is “within the

field of the inventor's endeavor." *Id.* at 442 (internal citations omitted). Specifically, the Examiner must "determine the appropriate field of endeavor by reference to explanations of the invention's subject matter in the patent application, including the embodiments, function, and structure of the claimed invention." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). Assessment of the field of endeavor must be supported by substantial evidence, *id.* at 1326, and must consider "'the reality of the circumstances,' in other words, common sense. . . ." *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992) (internal citations omitted).

Second, assuming the reference is outside of the applicant's field of endeavor, it must be determined whether the reference is "reasonably pertinent to the particular problem with which the inventor was involved." *In re Deminski*, 796 F.2d at 442 (internal citations omitted); *see also Ex parte Dussaud*, 7 U.S.P.Q.2d 1818, 1819 (Bd. Pat. App. & Int'f 1988) ("Precise definition of the problem is important in determining whether a reference is from a nonanalogous art."). In *In re Van Wanderham*, 378 F.2d 981 (C.C.P.A. 1967), the Board found that the invention (relating to methods to stabilize the flow of low-temperature rocket fuel) was analogous to a reference regarding how to make Japanese cutlery, because the problem facing the applicants was generally one relating to heat exchange, and thus, "heat exchange" is the pertinent art. *Id.* at 984. The Court reversed, finding that the applicants "are not chargeable with the knowledge set forth in the cutlery art." *Id.* at 988. The *Van Wanderham* case cautions that it is improper to define the problem to be solved too broadly so as to sweep in art that is not truly analogous.

One of skill in the art would not be motivated to combine *Brocchini* and *Neuenschwander* because these two references are non-analogous art. *Brocchini* is directed

to polymers for delivery of bioactive agents by oral, topical, systemic, or parenteral routes. (*Brocchini*, [0108]-[0109].) The polymers must be physiologically soluble and stable and suitable for incorporation into pharmaceutical solutions or pharmaceutical compositions. (*Id.* abstract, [0005]-[0007]; [0108], [0122].) Accordingly, the polyols that are incorporated into the polyacetal polymers are preferably polyethylene glycol or polypropylene glycol. (*Id.* [0091].) Such polyols are typically used in the pharmaceutical industry as formulation excipients. (*Id.* [0007].) They are hydrophilic polymers that are soluble in physiological media but are physiologically stable, i.e., they do not degrade *in vivo*. (*Id.*)

Neuenschwander is directed to block copolymers suitable for the production of medical implants. (*Neuenschwander*, abstract.) In contrast with *Brocchini*, *Neuenschwander* discloses block copolymers that have high mechanical strength and biological degradability. (*Id.* 1:15-19; 11:20-21.) The polymers are soluble in organic solvents, rather than water. (*Id.* 9:32-36.) Because the polymers are useful as medical implants, they must necessarily be insoluble in physiological media. Because the polymers of *Neuenschwander* are used as medical implants, they must have high mechanical strength, sterilizability, and biological degradability. (*Id.* abstract, 1:15-19.) Thus, *Brocchini* and *Neuenschwander* disclose inventions useful for different purposes which would have necessarily presented different problems to the inventors.

The Action broadly defines the technical difficulty addressed by *Brocchini* and *Neuenschwander* as “the preparation of biocompatible block copolymers containing conjugate bioactive compounds prepared from (macro)diols.” (Action, p. 5.) Applicant disagrees with this definition.

In determining the field of endeavor of an invention, embodiments, function, and structure must be considered. Accordingly, Applicant submits that the field of endeavor for *Brocchini* is polymers for delivery of bioactive agents where the polymers are soluble in physiological media and physiologically stable. In contrast, the field of endeavor for *Neuenschwander* is copolymers having high strength and biodegradability for medical implants.

Neuenschwander and *Brocchini* are in different fields of endeavor, and the polymers of *Neuenschwander* and *Brocchini* have different properties and are used in divergent applications, which necessarily presented the inventors with different problems. Thus, *Neuenschwander* and *Brocchini* are not analogous art, and one of skill in the art would not be motivated to modify *Brocchini* by replacing the physiologically-soluble, non-biodegradable polyols of *Brocchini* with the non-physiologically-soluble, non-water soluble, biodegradable polyester of *Neuenschwander*. Indeed, to do so would render the polymers of *Brocchini* insoluble in physiological environments and thus inoperable for their intended purpose. If a “proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” MPEP 2143.01, citing *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

The Action argues that *Neuenschwander* suggests that polyethers and polyesters are equivalent diols and therefore provides motivation for substituting polyesters for polyethers. Prior art references must be considered in their entireties, including portions that lead away from the claimed invention. See MPEP § 2141.02(VI). When considered in its entirety, *Neuenschwander* cannot be read to suggest that polyethers and polyesters are equivalent.

Conversely, *Neuenschwander* characterizes the two polymers as “chemically different.” (*Id.* 2:11-14.) Moreover, the copolymer of *Neuenschwander* is “built up from at least three components and has at least two chemically different block units which are joined to one another . . . i.e., α,ω -dihydroxypolyester and α,ω -dihydroxypolyether.” (*Id.* 2:9-14.) Thus, *Neuenschwander* does not teach that polyethers and polyesters are equivalent and exchangeable, but instead requires the presence of both of these “chemically different” polymers in its multi block copolymers.

For at least these reasons, it would not be obvious to modify the teachings of *Brocchini* in view of *Neuenschwander*. Accordingly, the Action has failed to establish a *prima facie* obviousness case. Claims 9, 10, 12, 13, and 16 are believed allowable.

D. Claim 11 is Patentable over Brocchini further in view of Shalaby

As explained above, *Brocchini* discloses degradable polyacetal polymers comprising a polyol block where the polyol is a polyether. (*Brocchini*, [0082]-[0086].) *Brocchini* fails to teach or suggest a polyol selected from a degradable carbonate (as recited in claim 11), as even the Action acknowledges. (Action, page 6.) The Action cites *Shalaby* as supplying a carbonate and argues that it would be obvious to modify *Brocchini* by substituting the carbonate of *Shalaby* for the polyether of *Brocchini*. One of skill in the art would not be so motivated because *Brocchini* and *Shalaby* are not analogous art and because making the substitution suggested by the Action would render the invention of *Brocchini* inoperable for its intended purpose. Furthermore, contrary to the Action’s argument, *Shalaby* does not provide motivation to make the suggested modification.

The standard for determining whether art is analogous to an invention was set out in detail above. Essentially, the art must either be within the same field of endeavor as the invention or must be relevant to the problem the inventor faced.

One of skill in the art would not be motivated to combine *Brocchini* and *Shalaby* because these two references are non-analogous art. As explained above, *Brocchini* is directed to polymers for delivery of bioactive agents by oral, topical, systemic, or parenteral routes. (*Id.* [0109].) The polymers must be physiologically soluble and suitable for incorporation into pharmaceutical solutions or pharmaceutical compositions. Accordingly, the polyols that are incorporated into the polyacetal polymers are preferably polyethylene glycol or polypropylene glycol. (*Id.* [0091].) Such polyols are typically used in the pharmaceutical industry as formulation excipients. (*Id.* [0007].) They are hydrophilic polymers that are soluble in physiological media but are physiologically stable, i.e., they do not degrade *in vivo*. (*Id.*)

Shalaby is directed to block copolymers suitable for the production of biomedical articles with controlled absorption and strength retention profiles. (*Shalaby*, 2:34-37.) In contrast with *Brocchini*, *Shalaby* discloses block copolymers that must have both high mechanical strength and flexibility. (*Id.* 2:47-50.) Because the polymers are useful as surgical articles such as sutures, clips, staples, pins, screws, and prosthetic devices (*Id.* 5:23-37), they must necessarily be insoluble in physiological media. Similar to those of *Neuenschwander*, the polymers of *Shalaby*, have high mechanical strength, flexibility and biological degradability. (*Id.* 2:26-27, 47-50.) Thus, *Brocchini* and *Shalaby* disclose

inventions useful for different purposes which would have necessarily presented the different problems to the inventors.

As explained above, in determining the field of endeavor of an invention, embodiments, function, and structure must be considered. The Examiner broadly defines the technical problem faced by the inventors of *Brocchini* and *Shalaby* as the preparation of biocompatible block copolymers prepared from diols. Applicant disagrees with this definition.

As discussed above, Applicant submits that the field of endeavor for *Brocchini* is polymers for delivery of bioactive agents where the polymers are soluble in physiological media and physiologically stable. In contrast to *Brocchini* the field of endeavor of *Shalaby* is absorbable copolymers with high strength and flexibility for medical devices.

Brocchini and *Shalaby* are in different fields of endeavor, and the polymers of *Brocchini* and *Shalaby* have different properties and are used in divergent applications, which necessarily presented the inventors with different problems. Thus, *Brocchini* and *Shalaby* are not analogous art, and one of skill in the art would not be motivated to modify *Brocchini* by replacing the physiologically-soluble, non-biodegradable polyols of *Brocchini* with the non-physiologically-soluble, biodegradable carbonate of *Shalaby*. Furthermore, to do so would render the polymers of *Brocchini* insoluble in physiological environments and thus inoperable for their intended purpose. If a “proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” MPEP 2143.01, citing *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

The Action argues that *Shalaby* provides motivation for the suggested modification by stating that the carbonate linkages provide biomedical articles having controlled absorption and reduced hydrolytic instability. Applicant respectfully disagrees with this interpretation of the reference. First, *Shalaby* does state that the copolymers described therein can be used to provide articles with controlled absorption and minimized hydrolytic instability, but *Shalaby* does not attribute these properties to the carbonate linkages. Second, *Shalaby* teaches that the copolymers also have controlled strength retention profiles important for the surgical articles that are made from the copolymers of *Shalaby*, but which would be inconsistent with solubility in a physiological medium as required of the polymers of *Brocchini*. As explained above, prior art references must be considered in their entireties, including portions that lead away from the claimed invention. See MPEP § 2141.02(VI). When the teaching of *Shalaby* is considered as a whole, *Shalaby* does not provide motivation to substitute carbonates for the polyether of *Brocchini*.

For at least these reasons, it would not be obvious to modify the teachings of *Brocchini* in view of *Shalaby*, and thus the Action has failed to establish a *prima facie* obviousness case. Claim 11 is believed allowable.

E. Claims 15 and 27 are Patentable over Brocchini in view of Wise

The disclosure of *Brocchini* is discussed above. *Wise* was cited for its teaching of buffers such as calcium phosphate and calcium phosphate fibers. The Action has failed to present a *prima facie* case of obviousness of claims 15 and 27 at least because the cited references do not teach or suggest all of the limitations of independent claim 1. Claims 15 and 27 depend from claim 1 or an intervening dependent claim and, therefore, incorporate the limitations of

claim 1. As amended, claim 1 recites a block copolymer comprising polyol residues connected by acetal linkages, where the polyol is selected from polyesters, degradable carbonates, and polyamides. *Brocchini* does not teach or suggest a copolymer comprising polyol residues connected by acetal linkages, where the polyol is selected from polyesters, degradable carbonates, and polyamides. *Wise* fails to cure this deficiency because *Wise* also does not teach or suggest a copolymer comprising polyol residues connected by acetal linkages, where the polyol is selected from polyesters, degradable carbonates, and polyamides. The Action has thus failed to present a *prima facie* case of obviousness at least because *Brocchini* and *Wise*, individually or in combination, do not teach or suggest a polyol selected from polyesters, degradable carbonates, and polyamides.

For at least these reasons, claims 15 and 27 are not obvious over *Brocchini* in view of *Wise*. Applicant respectfully requests reconsideration and withdrawals of these rejections. Claims 15 and 27 are believed allowable.

CONCLUSION

The amendments and the above remarks are believed fully responsive to the Office Action and place the claims in condition for allowance, which is respectfully requested.

No fees are believed due at the time; however, the Director is authorized by the paper to charge any fees due to deposit account number 11-0855. If there are any matters that can be addressed by telephone, the Examiner is respectfully urged to contact the undersigned attorney at 404-815-6040.

Respectfully submitted,



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